K113277

JUN 2 1 2012

5. 510(K) SUMMARY

1. Submitter Information

Name:	Arrow International, Inc (subsidiary of Teleflex Inc.)
Address:	2400 Bernville Road
	Reading, PA 19605-9607
Telephone Number:	(610) 378-0131
Contact Person:	Tracy Maddock
	Regulatory Affairs Specialist
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Date Prepared: November 4, 2011

2. Device Name

Device Trade Name:	ArrowADVANTAGE^{5}™ Pressure Injectable Peripherally Inserted Central Catheter (PICC)
Common Name:	Peripherally Inserted Central Catheter
Classification Name:	Percutaneous, implanted, long-term intravascular catheter

3. Predicate Devices

Predicate 1:	Pressure Injectable PICC (K061289)
Predicate 2:	Pressure Injectable PICC V2.0 (K073451)
Predicate 3:	6F 3L Pressure Injectable PICC (K080604)

4. Device Description

The ArrowADVANTAGE^{5}™ Pressure Injectable PICC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter is available in 4 Fr. single lumen and 5 Fr. double lumen configurations with usable lengths of 40 – 55 cm. The catheters can be used for the injection of contrast media. The maximum recommended infusion rate for the distal lumen is 5 mL/sec.

The catheters will be packaged sterile in both nursing and radiology configurations. Both configurations will include components to facilitate insertion.

5. Indications for Use

The ArrowADVANTAGE^{5}™ Pressure Injectable PICC is indicated for short-term or long-term peripheral access to the central venous system for intravenous therapy,

blood sampling, infusion, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the ArrowADVANTAGE^{5}™ Pressure Injectable PICC may not exceed 300 psi.

6. **Technological Characteristics and Substantial Equivalence**

The ArrowADVANTAGE^{5}™ Pressure Injectable PICC has the same indications for use, principles of operation and technological characteristics making it substantially equivalent to the Arrow predicate devices.

7. **Nonclinical Testing**

Bench testing was performed to demonstrate the ability of the proposed ArrowADVANTAGE^{5}™ Pressure Injectable PICC to effectively monitor for Central Venous Pressure.

8. **Conclusions**

Comparative analysis of technological characteristics between proposed and predicate devices and results of verification testing performed demonstrate that the subject device is substantially equivalent to the legally marketed predicate PICC devices. Any differences between the proposed and predicate devices do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2012

Ms. Tracy Maddock
Regulatory Affairs Specialist
Arrow International, Inc.
2400 Bernville Rd.
Reading, PA 19605

Re: K113277
Trade/Device Name: Arrow Advantages[5]™ Pressure Injectable Peripherally Inserted Central Catheter (PICC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: June 12, 2012
Received: June 13, 2012

Dear Ms. Maddock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113277

Device Name: ArrowADVANTAGE^{5}™ Pressure Injectable Peripherally Inserted Central Catheter (PICC)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 6/21/2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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